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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/017,697
Filing Date: December 07, 2001
Appellant(s): B. SANTOS ET AL.

Thomas T. Aquilla
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 03/10/05.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-20, 22-24, 26, 28-33 and 43-46 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

A substantially correct copy of appealed claims appears on page 12 of the Appendix to the appellant's brief. The minor errors are as follows: Claims 1-20, 22-24, 26, 28-33 and 43-46

stand rejected and appealable. Claims 35-42 were allowed. Claims 21, 25, 27 and 37 were objected to because these claims dependent on rejected claims.

(9) Prior Art of Record

5,431,916	WHITE	7-1995

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 8, 10, 11, 13, 15-19, 22-24, 26, 28-33 and 43-46 are rejected under 35 U.S.C. 102(b) as being anticipated by White (US 5,431,916).

White discloses a composition comprising a pharmaceutical, tri-ester, polyvinylpyrrolidone (abstract) and optionally polyethylene glycol having molecular weight of from about 300 to about 4,600 (column 6, lines 41-51 and column 7, lines 1 and 2). Few of the pharmaceutically active compounds in White's invention are analgesics, anti-inflammatory agents, anti-pyretics, calcium channel blockers, beta-blockers and expectorants and antitusives (column 5, lines 25-62); and specific examples are acetaminophen, ketoprofen, naproxen, ibuprofen, pseudoephedrine, dextromethorphan, guaifenesin, doxylamine, phenylpropanolamine, chlorpheniramine, antibiotics, antivirals and caffeine and pharmaceutically acceptable salts and mixtures thereof (column 5, line 63 to column 6, line 7). The composition formulated as

solution is buffered to pH of about 7 (column 8, lines 5-12). The composition may further contain glycerin, sorbitan, sorbitol (column 8, line 60), colorings, flavorings, preservatives, antioxidants and essences (column 9, lines 11 and 12). Polyvinylpyrrolidone ranges from 17.14% to 29.36% in examples III to VIII and in column 4, lines 52-56; the polyvinylpyrrolidone is disclosed to be present from about 10% to about 50%. The pharmaceutical is present from about 0.01-50%. Instant claim 15 recites the intended use of the composition and in a composition claim a future intended has no patentable weight. The comprising language of the instant claims does not exclude the presence of the tri-ester from the instant claimed composition. The instant method recited in claim 43 merely combines the ingredients to form the composition disclosed in the prior art. The teaching disclosed in White meets the limitations of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5, 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over White (US 5,431,916).

White teaches the instant composition as discussed above except that White fails to teach the amount of polyethylene glycol. However, White discloses that polyethylene glycol may be employed to facilitate the solubility of actives or modify the viscosity of suspensions (column 7, lines 24-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time

the invention was made to use an appropriate amount of polyethylene glycol. One having ordinary skill in the art would have been motivated to modify the composition of White by using an amount of polyethylene glycol in the composition that would be expected to facilitate the solubility of actives or modify the viscosity of suspensions in order to provide a composition having the desired viscosity.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over White (US 5,431,916).

White teaches the instant composition except that the amount of polyvinylpyrrolidone in White's composition is greater than the 7% recited by the claim. However, White discloses that polyvinylpyrrolidone is a solubilizing or suspending system in combination with the tri-ester (column 4, lines 65-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an amount of polyvinylpyrrolidone that would be expected to combine with desired amount of the tri-ester to provide the solubilizing and suspending system suggested by the prior art. One having ordinary skill in the art would have been motivated to modify the composition of the prior art by employing polyvinylpyrrolidone in amounts that will in combination with the tri-ester provide a solubilizing and suspending system in which the ingredients of the composition are appropriately solubilized and suspended to yield the expected liquid composition.

Claims 12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over White (US 5,431,916).

White discloses the instant composition except that White fails to disclose the amount of sweetening agents recited in instant claim 12. Regarding instant claim 20, the specific

antibiotics recited are encompassed in the generic antibiotic teaching disclosed in the prior art. Since sweetening agents are known to be used to mask the taste of bitter tasting medicines such as acetaminophen, it would be necessary to use an appropriate amount of the sweetening agent that will mask the taste. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the composition of White with an amount of sweetening agent to mask the taste of acetaminophen, say. One having ordinary skill in the art would have been motivated to modify White's composition by employing sweetening agent in amounts that would be expected to mask the taste of bitter tasting medicines.

Claims 21, 25, 27 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not disclose composition comprising the drugs recited in claims 21, 25, 27 and 34.

Allowable Subject Matter

Claims 35-42 are allowable because the prior art does not disclose the specific compositions recited therein.

In the FINAL REJECTION, claims 1-4, 7, 8, 10, 11, 13, 15-19, 22-24, 26, 28-33 and 43-46 remain rejected under 35 U.S.C. 102(b) as being anticipated by White (US 5,431,916).

Applicants argue that White does not teach a liquid composition or the method of preparing a liquid composition and that White's composition is encapsulated and cannot thus be administered as a liquid. Applicants state that the examples in White disclose compositions and methods for the making of pharmaceuticals that are encapsulated within soft gelatin capsules.

Applicants conclude that because White does not disclose each and every element of the claims 1 and 43 amended to say that the formulation is administered in liquid form, White cannot anticipate claims 1 and 43 and the claims dependent therefrom. Applicants then referred to the declaration by Dr. Kennie U. Dee.

Applicants' arguments filed 04/30/04 were fully considered but they are not persuasive.

Applicants' attention is respectfully directed to White (US 5,431,916), column 8, lines 8-12, which states that "after the final mixture has been formulated, if a solution, the mixture should be buffered as close to neutral as possible without precipitating the pharmaceutically acceptable active. If the final composition is to be a suspension, the formulation should be buffered to a pH of about 7. Buffering to approximately a neutral pH stabilizes the ester component of the invention reducing any tendency toward hydrolysis." Specifically in column 7, line 58, White states that if a solution is the desired form of the formulation, additional heat may be required to facilitate the dissolution of the pharmaceutically acceptable active. Solution is a liquid. Thus, it is clear from the foregoing that White discloses formulating the composition that are liquid or solution or suspension. Applicants' attention is also respectfully directed to examples I and V where it is stated "the resulting composition is suitable for oral administration, and encapsulation within soft gelatin shells." These examples disclose the preparation of solutions that can be administered orally or than can be encapsulated within soft gelatin capsules. The solutions/liquids of White are not only encapsulated in soft gelatin capsules as recognized by applicants, but the solutions/liquids can be administered as stated in examples I and V. Also, liquids and not solid formulations are put into the soft gelatin capsules and the soft gelatin capsule serves to mask the taste of the bitter tasting medicament.

Also, in the FINAL REJECTION, the rejection of claims 5, 6, 9, 12,14 and 20 under 35 U.S.C. 103(a) as being unpatentable over White (US 5,431,916) was addressed together. Here applicants referred back to the argument presented in the rejection under 35 USC 102(b) and to the declaration by DR. Kennie U. Dee. Furthermore, applicants state that the instant invention addresses the problem of "the unpleasant taste of a drug in a liquid format, where the liquid composition is a syrup, a ready-to-use suspension, or extemporaneously prepared liquid syrup or suspension such as, for example, dry powder for reconstitution with water, liquid concentrate for dilution, dispersible tablet or capsule" and that the taste-masked liquid composition has substantially reduced bitter taste and after taste. Applicants say the White's invention is an encapsulated composition and that all of the examples disclose pharmaceuticals encapsulated within soft gelatin capsules and are thus not administered in liquid form. Applicants state that White's composition is a solid at room temperature and the composition is a bitter-tasting solid so that White does not teach or suggest a liquid composition or the taste masking thereof according to Dr. Kennie U Dee's declaration. Applicants also argue that White does not use polyethylene glycol to create a taste-masked composition but uses polyethylene glycol to solubilize certain pharmaceuticals. Applicants also state that White uses polyvinylpyrrolidone as a solubilizng or suspending agent in combination with tri-ester and not as a taste-masking agent. Applicants then argue that White does not teach or suggest claim 1 and therefore does not teach or suggest dependent claims 5, 6, 9, 14 and 20.

Applicants' arguments filed 04/30/04 were fully considered but they are not persuasive.

Applicants' arguments center around the theme that White does not disclose a liquid composition. It was pointed out in the discussion above under 35 USC 102(b) that White

discloses solution and suspensions in final form that are suitable for administration and encapsulation within soft gelatin capsules. White (column 8, lines 8-12) states "after the final mixture has been formulated, if a solution, the mixture should be buffered as close to neutral as possible without precipitating the pharmaceutically acceptable active. If the final composition is to be a suspension, the formulation should be buffered to a pH of about 7. Buffering to approximately a neutral pH stabilizes the ester component of the invention reducing any tendency toward hydrolysis." Specifically in column 7, line 58, White states that if a solution is the desired form of the formulation, additional heat may be required to facilitate the dissolution of the pharmaceutically acceptable active. Solution is a liquid. Thus White discloses formulating the composition as a liquid or solution or suspension. Applicants' attention is also respectfully directed to examples I and V where it is stated "the resulting composition is suitable for oral administration, and encapsulation within soft gelatin shells." These examples disclose the preparation of solutions that can be administered orally or than can be encapsulated within soft gelatin capsules. The solutions/liquids of White are not only encapsulated in soft gelatin capsules as recognized by applicants, but the solutions/liquids can be administered as stated in examples I and V. Also, liquids and not solid formulations are put into the soft gelatin capsules.

Regarding polyethylene glycol, the polyethylene glycol cannot do one thing in one composition and do another in another composition. At best, what will happen is that the polyethylene glycol can perform both functions that applicants are according the glycol, that is, act as a taste-masking agent and also as a solubilizing agent. Applicants failed to provide the conditions in which the polyethylene glycol can act only as a taste-masking agent as applicants argue and the condition under which the polyethylene glycol will act as a solubilizing agent.

Applicants claim a composition that comprises an unpleasant tasting drug, polyethylene glycol and polyvinylpyrrolidone (instant claim 1) and a method of preparing the composition (instant claims 43). A prior art's composition that meets the limitations as set forth would have the properties of that composition. The polyethylene glycol and polyvinylpyrrolidone of the prior art will accord to the composition of the prior art what the polyethylene glycol and the polyvinylpyrrolidone would do to the instant composition. Thus, in essence, because the composition of the prior art is the same as the instant composition, the bitter taste of the composition of the prior art would be masked. Applicants' composition uses the language of comprising and the comprising language does not exclude the presence of the tri-ester. If polyethylene glycol and polyvinylpyrrolidone are taste-masking agents in the instant case, the polyethylene glycol and polyvinylpyrrolidone will also mask the taste of the bitter or unpleasant tasting drug. All the examples in White do not disclose solids, rather, the examples disclose solutions/suspensions/liquids and that these forms can be administered orally or encapsulated. It is also respectfully noted that the capsule serves to mask the taste of the liquid formulation contained in the capsule.

Dr. Kennie U. Dee's declaration:

Dr. Kennie U. Dee declares that White does not disclose a taste-masked liquid pharmaceutical composition but discloses encapsulated formulations that are not administered in liquid form.

On the contrary, White discloses solution or suspension formulations that are suitable for oral administration or encapsulation within soft gelatin capsules (column 10, lines 37 and 38; column 11, lines 38 and 39) and liquid or solution or suspension is contained in the capsule and not solid.

Dr. Kennie U. Dee declares that most of the examples in White are compositions and methods for manufacture of pharmaceuticals that are encapsulated within soft gelatin capsules.

On the contrary, the examples in White disclose preparation of solution/suspensions that can be administered orally or that can be encapsulated within soft gelatin capsules. It is noted that example II of White is the example that specifically discloses "using the resulting solution ...to prepare soft gelatin capsules."

Dr. Kennie U. Dee declares that the compositions of White are bitter tasting and referred to exhibit 2.

The instant composition does not exclude the presence of tri-esters. The exhibit does not present a parallel example where the tri-ester of White is included in the instant composition. The tasting experiment thus focused on the composition of the prior art and not on the instant composition, which does not exclude tri-esters.

Dr. Kennie U. Dee declares that tri-esters are essential component in White and that the tri-esters are viscous liquids with a bitter taste.

Applicants' claimed invention does not exclude tri-esters in the instant composition.

Dr. Kennie U. Dee declares White does not disclose each and every element of claim 1 and 43 and their dependent claims.

White discloses a composition that comprises tri-ester, polyvinylpyrrolidone, polyethylene glycol and a pharmaceutical agent that has a bitter taste. The instant claims do not exclude tri-esters from the composition and thus White discloses the limitations of claims 1 and 43.

Dr. Kennie U. Dee declares that Examiner's conclusion is incorrect because success cannot be reasonably expected by modifying White to arrive at the claimed invention in dependent claims 5, 6, 9, 12, 14 and 20 for the reasons that follow:

White does not disclose taste-masking or improving the taste of unpleasant tasting drug, Whites disclosure is limited to solvent systems with significant solvating properties that are able to dissolve relatively large quantities of pharmaceutical actives at high temperatures, Whites composition requires the inclusion of tri-esters that are bitter tasting that increases the amount of bitter tasting drugs and also increases the bitter taste of drugs that can be detected by the human tongue, and White's disclosure is strictly limited to compositions and methods for manufacture of pharmaceuticals that are encapsulated within soft gelatin capsules, White's disclosure is not sufficient to teach applicants' claimed taste-masked liquid pharmaceutical compositions.

White's disclosure is sufficient and teaches the instant claimed invention because White discloses the composition of the instant claims and because the claims fail to exclude the tri-esters of White, the composition of White is the same as the instant composition. The study conducted failed to run a parallel composition with the composition of White where the tri-ester of White is included in the instant composition. The scope of applicants' composition is not met by the study as it excludes the tri-esters from the instant composition.

In the FINAL REJECTION , claims 21, 25, 27 and 34 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims because the prior art does not disclose composition comprising the drugs recited in said claims.

In the FINAL REJECTION , claims 35-42 remain allowable because the prior art does not disclose the specific compositions recited therein.

(11) Response to Argument

Appellant argues that White does not disclose each and every element of Appellants' independent claims 1 and 43 because:

a) "Appellant's use of open language in the preamble is not particularly relevant," and the issue is that the prior art relied upon by the Examiner does not disclose each and every element of the claim since White does not disclose any taste-masked liquid. Appellant states that anticipatory rejection can be avoided if it is shown that at least one element is not disclosed by the prior art.

In the present case, the claims 1 and 2 are directed to liquid pharmaceutical composition and the method for preparing the said composition, the composition comprises at least one unpleasant tasting drug, a polyethylene glycol having molecular weight of at least 900 and polyvinylpyrrolidone and/or copolyvidone, where "a final form of the said taste-masked pharmaceutical composition administered to a patient is a liquid." The prior art does not have to specifically state that a composition is taste-masked, but a prior art that discloses a composition that comprises at least one unpleasant tasting drug, a polyethylene glycol having molecular weight of at least 900 and polyvinylpyrrolidone and/or copolyvidone meets the limitation and because the open language of "comprising" permits the presence of ingredients other that the three listed, the prior art's composition can contain other ingredients and still meet the limitations. Also, a composition that comprises at least one unpleasant tasting drug, a

polyethylene glycol having molecular weight of at least 900 and polyvinylpyrrolidone and/or copolyvidone must necessarily be taste-masked except there is a particular and specific combination that excludes the composition of the prior art. In this particular case, the comprising language of the instant claims does not exclude other ingredients. A consisting essentially of language will limit the instant composition to the recited components and exclude other components that would materially affect the novel characteristics of the composition. Thus the comprising language allows for the presence of components/ingredients other than the three recited.

b) Appellant states that the composition of the prior art is bitter because of the presence in the composition of tri-esters and that this difference alone clearly distinguishes the claimed composition from that of the prior art because White's composition is bitter and that of Appellant is non-bitter.

Appellant's composition does not exclude the tri-ester of the prior art because of the use of the "comprising" language in the claimed composition. The capsule functions to mask the taste; the presence of the tri-esters in the composition of the prior art does not provide a composition that is distinct from the claimed composition because the comprising language of the claims permits the presence of the tri-esters in the composition.

Appellant argues that White fails to raise a prima facie case of obviousness against claims 5, 6, 9, 12, 14 and 20 and that the Examiner fails to establish that the prior art provides some teaching, suggestion or motivation to combine or modify the cited references, Examiner is using impermissible hindsight, failing that. Examiner failed to show that one of ordinary skill in the art would have reasonably expected success in making the invention and that Examiner is

expected to support the obviousness rejection with actual evidence, as opposed to mere conclusory statements.

The difference between the claimed composition and the prior art is amount of polyethylene glycol (claims 5, 6 and 14), the amount of polyvinylpyrrolidone (claim 9) and the amount of the sweetening agents (claims 12 and 20). Generally, differences in amounts of polyethylene glycol (claims 5, 6 and 14), the amount of polyvinylpyrrolidone (claim 9) and the amount of the sweetening agents (claims 12 and 20) will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount provides unusual and unexpected results. "W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Appellant fails to show that those amounts recited in the designated claims provided unusual and unexpected results to the claimed composition. White suggests that polyethylene glycol may be employed to facilitate the solubility of actives or modify the viscosity of suspensions (column 7, lines 24-30). Thus the person of ordinary skill in the art would be motivated to use the amount of the polyethylene glycol that would be expected to facilitate the solubility of actives or modify the viscosity of suspensions in order to provide a composition having the desired viscosity. This is not mere conclusory statement. Appellant fails to provide data showing how the recited amount of polyethylene glycol provide unexpected results.

White discloses that polyvinylpyrrolidone is a solubilizing or suspending system in combination with the tri-ester (column 4, lines 65-67). And one having ordinary skill in the art would have been motivated to modify the composition of the prior art by employing

polyvinylpyrrolidone in amounts that will in combination with the tri-ester provide a solubilizing and suspending system in which the ingredients of the composition are appropriately solubilized and suspended and would be expected to yield the expected liquid composition. Appellant fails to provide unexpected data to show that the recited amount of the polyvinylpyrrolidone provides unusual results.

Sweetening agents are known to mask the taste of bitter tasting medicines such as acetaminophen. It would be necessary to use appropriate amount of the sweetening agent that will mask the taste. One having ordinary skill in the art would have been motivated to modify White's composition by employing sweetening agent in amounts that would be expected to mask the taste of bitter tasting medicines.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to appellant's argument that there is no suggestion to combine or modify the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071,

5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, suggestion and motivation are both found in the prior art and in the knowledge generally available to the one of ordinary skill in the art.

The prior art discloses a liquid formulation comprising a drug, polyvinylpyrrolidone and trimesters, the liquid is encapsulated and the capsule functions to mask the taste. Applicants' comprising language does not exclude the presence of tri-esters. The solution or suspension of White is suitable for oral administration and the encapsulation functions to mask the taste.

Dr. Kennie U. Dee's declaration:

Dr. Kennie U. Dee declares that White does not disclose a taste-masked liquid pharmaceutical composition but discloses encapsulated formulations that are not administered in liquid form.

On the contrary, White discloses solution or suspension formulations that are suitable for oral administration or encapsulation within soft gelatin capsules (column 10, lines 37 and 38; column 11, lines 38 and 39) and liquid or solution or suspension is contained in the capsule and not solid.

Dr. Kennie U. Dee declares that most of the examples in White are compositions and methods for manufacture of pharmaceuticals that are encapsulated within soft gelatin capsules.

On the contrary, the examples in White disclose preparation of solution/suspensions that can be administered orally or that can be encapsulated within soft gelatin capsules. It is noted that example II of White is the example that specifically discloses "using the resulting solution ...to prepare soft gelatin capsules."

Dr. Kennie U. Dee declares that the compositions of White are bitter tasting and referred to exhibit 2.

The instant composition does not exclude the presence of tri-esters. The exhibit does not present a parallel example where the tri-ester of White is included in the instant composition. The tasting experiment thus focused on the composition of the prior art and not on the instant composition, which does not exclude tri-esters.

Dr. Kennie U. Dee declares that tri-esters are essential component in White and that the tri-esters are viscous liquids with a bitter taste.

Applicants' claimed invention does not exclude tri-esters in the instant composition.

Dr. Kennie U. Dee declares White does not disclose each and every element of claim 1 and 43 and their dependent claims.

White discloses a composition that comprises tri-ester, polyvinylpyrrolidone, polyethylene glycol and a pharmaceutical agent that has a bitter taste. The instant claims do not exclude tri-esters from the composition and thus White discloses the limitations of claims 1 and 43.

Dr. Kennie U. Dee declares that Examiner's conclusion is incorrect because success cannot be reasonably expected by modifying White to arrive at the claimed invention in dependent claims 5, 6, 9, 12, 14 and 20 for the reasons that follow:

White does not disclose taste-masking or improving the taste of unpleasant tasting drug, Whites disclosure is limited to solvent systems with significant solvating properties that are able to dissolve relatively large quantities of pharmaceutical actives at high temperatures, Whites composition requires the inclusion of tri-esters that are bitter tasting that increases the amount of bitter tasting drugs and also increases the bitter taste of drugs that can be detected by the human tongue, and White's disclosure is strictly limited to compositions and methods for

manufacture of pharmaceuticals that are encapsulated within soft gelatin capsules, White's disclosure is not sufficient to teach applicants' claimed taste-masked liquid pharmaceutical compositions.

White's disclosure is sufficient and teaches the instant claimed invention because White discloses the composition of the instant claims and because the claims fail to exclude the tri-esters of White, the composition of White is the same as the instant composition. The study conducted failed to run a parallel composition with the composition of White where the tri-ester of White is included in the instant composition. The scope of applicants' composition is not met by the study as it excludes the tri-esters from the instant composition.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Bf
June 25, 2005

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